GUEST EDITORIAL

The Expanding Role of the Office Laboratory

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Technology, reimbursement policies, and the entrepreneurial success of laboratory equipment companies are combining to produce significant changes in medical testing. In the midst of what has recently been described as a "quiet revolution," one half of all outpatient clinical laboratory procedures are now performed in office laboratories.[1] Sales data indicate that an increasing number of physicians are choosing the convenience of basing their medical decisions on test results that are available before a patient leaves the office.

The new rapid tests for detecting group A streptococcal antigen directly from a throat swab, the subject of two articles in this issue,[2,3] are paradigms in the progress of this revolution. For patients with no special risk factors, these tests offer a cost-effective alternative in the management of a common clinical problem.

Upper respiratory tract infection, including pharyngitis, is the most frequent acute medical problem that leads patients to consult their family physicians.[4] Until recently the throat culture, with an inherent delay of one to two days, was the only reliable option for diagnosing group A β-hemolytic streptococcal pharyngitis. Improvements in the technology of rapid tests have made it possible to identify the presence of group A streptococcal antigens and to start antibiotic treatment promptly without exposing all patients to the risk of an allergic reaction while waiting for a culture result.

Opinions are divided on the role of the new streptococcal tests. In a number of clinical trials[5] sensitivities have ranged from 0.81 to 0.95 with specificities from 0.91 to 1.0. These results match the accuracy of carefully performed office cultures. The accepted sensitivity of a "gold standard" serologically confirmed culture from a reference laboratory is approximately 0.9, and the specificity is 1.0. One authority, concerned about the variation of sensitivity and specificity in different clinical trials and about the limited experience with the new tests, has suggested confirming all negative rapid tests with a culture.[6] Many other physicians, impressed by the improved efficiency in managing pharyngitis, are now basing treatment decisions solely on rapid tests. It is important for physicians considering the use of these new tests to conduct their own clinical trials to verify the accuracy when performed by office personnel.

The opportunity to diagnose streptococcal pharyngitis before the patient leaves the office may raise or lower the cost of testing, depending on the culture method that the rapid test replaces. The cost of a typical rapid test is approximately $2, about $1 more than the materials for an office culture. At the high end of the price scale, the charge for a serologically confirmed culture in a reference laboratory varies. At the University Hospital in Seattle it is approximately $20. As a market force, the availability of rapid office tests

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may lower the cost of reference laboratory cultures.

The shift toward office laboratory testing presents both opportunities and responsibilities. Some of these tests can improve the cost effectiveness and quality of the care we provide for our patients. They also offer an opportunity to perform office-based research that can effect changes in the standards of care.

Physicians faced with aggressive marketing techniques need to maintain a healthy skepticism about the role of new tests. In the interests of our patients' welfare, we should evaluate tests as carefully as we consider the use of a new medication. We must be prepared to defend our decisions legally and to comply with regulations regarding the conduct of an office laboratory.

In their role as office laboratory director, physicians will need to face the issues of accuracy, quality control, personnel training, safety, and the economics of testing.[7] The concept of test sensitivity should be a practical concern before a patient develops rheumatic fever or a suppurative complication of streptococcal pharyngitis when a test has been falsely negative. Specificity is more than an academic detail when asking whether the patient with a severe allergic reaction to penicillin received the medication because of a falsely positive test.

Educators need to prepare medical students and residents for their future responsibilities as an office laboratory director. The relevant skills and concepts of basic laboratory science should be incorporated into their training.

Research in family practice "is an essential element in the development of the specialty,"[4] and it should meet the need for critical evaluation of evolving test technology. A new test should be judged in the setting where it will be used because the predictive value depends on the population tested and on the level of skill required of the operator. The article by Fischer and Mentrup[2] in this issue exemplifies this principle by demonstrating that the accuracy of a rapid streptococcal test is preserved in an office laboratory. Their study differs from most previous clinical trials where the tests were performed by trained medical technicians. Busy physicians will find the results of such research highly relevant as they participate in a "quiet revolution" that is just beginning.

References

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